DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 15, 2014

Cartiva, Incorporated
% Ms. Rachel Kennedy
Principal Advisor
Regulatory and Clinical Research Institute
5353 Wayzata Blvd, Suite 505
Minneapolis, Minnesota 55416

Re: K142490
Trade/Device Name: ProxiFuse Hammer Toe Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: September 15, 2014
Received: September 17, 2014

Dear Ms. Kennedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142490

Device Name
ProxiFuse Hammer Toe Device

Indications for Use *(Describe)*
The ProxiFuse Hammer Toe Device is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Patients should be protected weight-bearing or heel-bearing until fusion or healing has occurred.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional 510(k) Summary

Submitted by:
Cartiva, Inc.
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Alpharetta, GA 30005

Contact Person:
Rick Knostman
Vice President, Operations
Cartiva, Inc.
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Date of Summary: November 25, 2014

Device Trade Name: ProxiFuse Hammer Toe Device

Model Number: PRF-01

Product Code: HWC, HTY

Common or Usual Name: Screw, Fixation, Bone

Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Predicate Device(s):
Pro-Toe VO Hammertoe Implant System, K101165
NEWDEAL K WIRE, K022599
Arthrex Bio-Pin (marketed as Trim-It Pin), K050259

Device Description: The ProxiFuse Hammer Toe Device consists of three components: 1) the implant, 2) deployment instrumentation, and 3) bone awl. The implant is comprised of 2-0 suture, two Nitinol anchors with PEEK Inserts, and a PEEK Stabilizing Body. The device is delivered through a specifically designed instrument. The method of delivery allows for a shifting of the PEEK Body which limits the amount of traction required to place the middle phalanx over the device. The suture utilized in the device serves multiple functions: 1) shifting of the PEEK Body and 2) applying tension between the Nitinol anchors which in turn stabilizes the proximal interphalangeal joint (PIPJ).

Indication for Use: The ProxiFuse Hammer Toe Device is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Patients should be protected weight-bearing or heel-bearing until fusion or healing has occurred.

Technological Characteristics:

The technological characteristics of the ProxiFuse Hammer Toe Device differ from predicates in the multicomponent design and use of polymer materials in combination with nitinol anchors to achieve stable fixation to enable fusion. Despite the differences in device shape, fundamental scientific technology, materials and method of delivery, standard test methods exist to demonstrate equivalent performance with respect to fixation (Pullout/Dis-assembly Testing) and stability (Static and Fatigue Bending Testing). By applying acceptable methods to evaluate effects on safety and effectiveness, substantial equivalence to the predicates is established.

Performance Testing Summary:

Bench testing was performed to assure substantial equivalence to a predicate device and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. No clinical data were needed to support the safety and effectiveness of the subject device.

Bench testing consisted of the following:

- USP Suture Testing
- Pullout/Dis-assembly Testing
- Static Bending Testing
- Fatigue Bending Testing
- Bench and Cadaver Testing

Conclusion:

The ProxiFuse Hammer Toe Device is substantially equivalent to the named predicates based on technological comparison, indications for use, and laboratory and other safety testing. It is concluded that there are no new questions of safety and effectiveness.